

**REMARKS/ARGUMENTS**

Upon entry of the present amendment, claims 81-86, 89-90, 92, 94-108, 112-113, 121-130, 132, 134-137, 140, 150, 160-171, 173, 177-180, 182-198, and 200-235 are pending in the application; of which claims 90, 99, 187, 189, 204-205, and 207 have been withdrawn from consideration as being directed to non-elected subject matter. Claims 81, 97, 121, 132, 160, 182, 192-194, 212, 214 and 218 are amended, and claims 1-80, 87-88, 91, 93, 109-111, 114-120, 131, 133, 138-139, 141-149, 151-159, 172, 174-176, 181, 191 and 199 are canceled. Claims 81-86, 89, 91-98, 100-108, 112-113, 121-130, 132, 134-137, 140, 150, 160-171, 173, 177-180, 182-186, 188, 190-198, 200-203, 206, and 208-221 stand finally rejected by the Examiner. Applicants respectfully request reconsideration in view of the RCE filed herewith and the claim amendments and remarks herein below.

**Election/Restrictions**

Applicants acknowledge the withdrawal from prosecution of the following claims as direct to non-elected species: 90, 99, 187, 189, 204,205 and 207. Applicants reserve the right to prosecute the subject matter of the restricted claims in subsequent divisional and continuation applications.

**Claim Rejections - 35 USC §112**

Claims 81-86, 89, 91-98, 100-108, 112-113, 121-130, 132, 134-137, 140, 150, 160-171, 173, 177-180, 182-186, 188, 190-198, 200-203, 206, and 208-221 are rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action pages 2-4. Applicants have amended these claims to remove the limitation “without creating an epithelial flap”, such that these rejections are overcome.

Claims 81-86, 89, 91-98, 100-108, 112-113, 121-130, 132, 134-137, 140, 150, 160-171, 173, 177-180, 182-186, 188, 190-198, 200-203, 206, and 208-221 are rejected under 35 USC §112, second paragraph, as allegedly indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. Office Action page 4. Applicants have amended these claims to remove the limitation “without creating an epithelial flap”, such that these rejections are overcome.

### **Claim Rejections - 35 USC §103**

Claims 81-85, 89, 91-92, 94-95, 97-98, 105-106, 108, 182-183, 185, 188, and 191 were rejected under 35 USC §103(a) as allegedly obvious over WO02/06883 in the name of Perez (hereinafter "Perez") in view of US 5,171,318 in the name of Gibson et al. (hereinafter "Gibson") or US 4,676,790 in the name of Kern (hereinafter "Kern") and US 5,547,468 in the name of Simon et al. (hereinafter "Simon") or US 4,636,210 in the name of Hoffer (hereinafter "Hoffer"). Office Action pages 4-5. These claims are amended and this rejection is overcome as explained below.

Claim 81 has been amended to recite, in addition to other claim elements, that the lens is substantially fixed to the eye by the epithelium when the lens is inserted into the pocket. The support use and advantages of amended claim 81 can be found throughout the application as originally filed on September 12, 2003 (hereinafter "Application"), and in particular with references to Figures 2, 7A-7C, 8A-8C and 13A-13C and the supporting text on pages 5-7, 9 and 15. For example, the Application states, "In addition, a corneal appliance may be obtained by a process of inserting a lens underneath an epithelium of an eye substantially without exposing or uncovering the underlying corneal surface and allowing the epithelium to be fixed secured over the lens." Application, page 5, line 31 to page 6, line 2. Further, the application also states, "For example, the epithelial cells may be a portion of an epithelial pocket, such as, a portion of a preformed layer of epithelium that is located in proximity to where the layer of the epithelium begins to separate from the Bowman's membrane or stroma of the eye." Application page 7, lines 14-19. The Application also notes the advantages of inserting the lens into the pocket as recited in claim 81, "The corrective ocular device, such as a corneal onlay, may then be inserted between the epithelium and Bowman's membrane. Advantageously, in this embodiment, the epithelium is not required to be realigned after insertion of the ocular device, an misalignment

problems of the ocular device are reduce.” Application, page 15, lines 16-22. With reference to the embodiments described in Figures 7A-7C, the Application states, “By inserting an ocular device beneath an epithelium but on or above the stroma or Bowman’s membrane, the ocular device is effectively substantially fixedly positioned with respect to the eye, for example, by the epithelium, to provide the desired vision correction. In addition, this method provides for relatively enhanced healing or reduced times and reduced side effects relative to methods that produce a flap of epithelial tissue to insert an ocular device.” Application, page 39, line 30 to page 40, line 6. Examples of vision correction that can benefit from the lens substantially fixed to the eye by the epithelium as described in the present application include, for example, astigmatism correction, wavefront aberration correction, the correction of presbyopia, myopia and hyperopia. Application, page 16, lines 21-26, Figures 13A-13C, page 17, lines 12-16, page 27, lines 3-6.

Under 35 U.S.C. §103(a) a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. M.P.E.P. § 2141. The Supreme Court in Graham v. John Deere Co. clarified that a rejection under §103 requires that the scope and content of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and that the level of ordinary skill in the art be resolved. [383 U.S. 1, 17, 148 USPQ 459, 467 (1966)] Recently, in KSR v. Teleflex, the Court affirmed the standard of Graham. [82 USPQ2d 1385 (2007)]

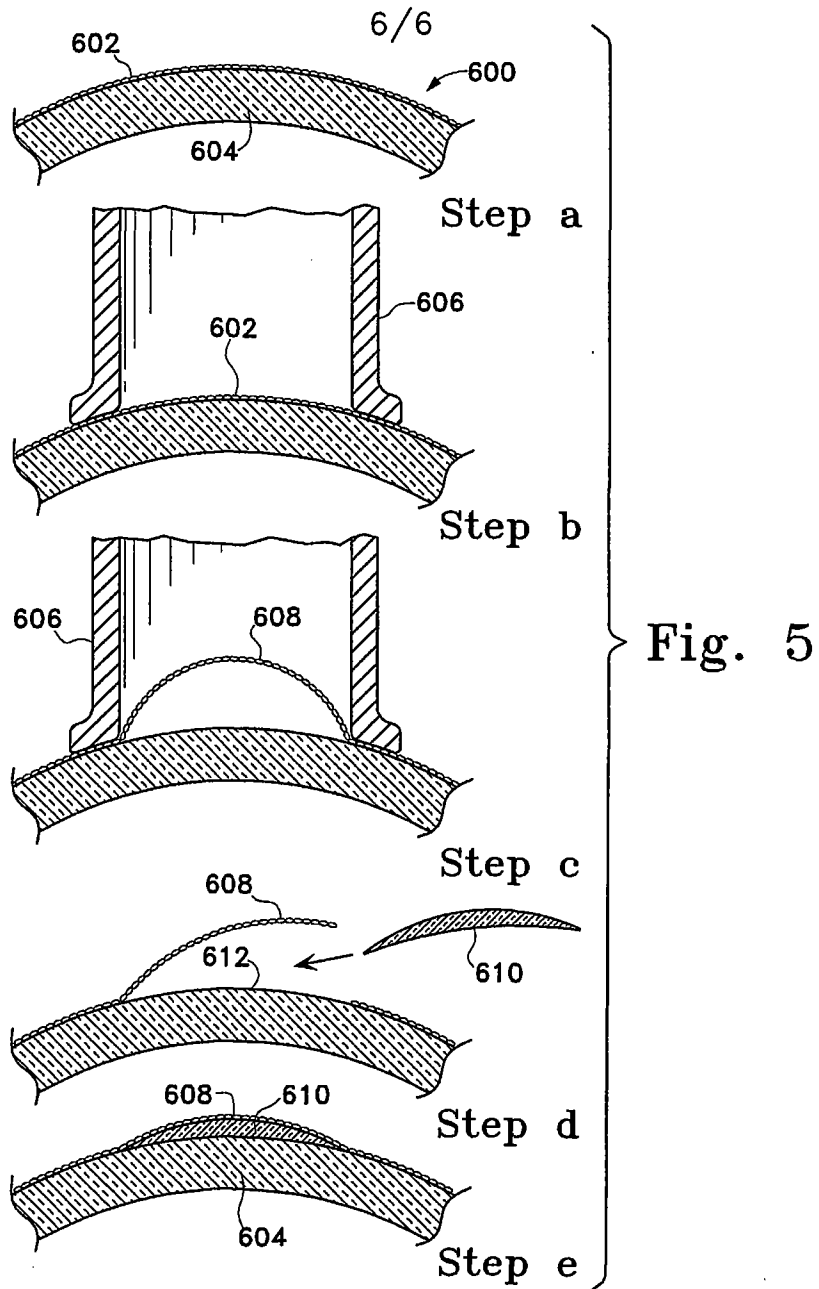
The lens substantially fixed to the eye with the epithelial cell layer, as recited in claim 1, is a significant and unobvious difference between the scope and content of the proposed combination of Perez in view of Gibson or Kern and Simon or Hoffer.

The relevant scope and content Perez is directed to creating an epithelial flap. For example, the text supporting Figure 5 states,

Step b. of fig. 5 shows the placement of a suction device (606) on the anterior surface of the eye (600). The suction device (606) applies a modest vacuum to the epithelial layer (602), e. g., between about -100 mmHg and -450 mmHg, to raise a section of the epithelial

layer (602) as shown in step c. This blister (608) typically is filled with a physiologic fluid. Obviously, the suction device (606) has a footprint on the surface of the cornea similar to the size of the lens to be placed on that cornea. Step d. shows the opened epithelial flap (608) and the placement of the lens towards the corneal stromal margin (612) beneath that epithelial flap (608). Step c. of Fig. 5 shows the finished placement of the lens (610) on the cornea beneath the native epithelial membrane. Perez, page 19, lines 1-16.

Applicants have pasted Figure 5 of Perez below for the Examiner's convenience.



The Examiner has stated, "Perez teaches a method of creating a pocket between the epithelial layer of the Bowman's membrane and then inserting a lens therein before the closure thereof; see Figures 5 and page 19, lines 1-16. Office Action, page 5.

Claim 81 recites that the lens is substantially fixed to the eye with the epithelium, and Applicants fail to see how Perez teaches fixation of the lens to the eye with the epithelium. Perez teaches the formation of a blister (608) and a flap (608), such that the blister and flap of Perez are incapable of substantially fixing the lens to the eye with the epithelium as recited in claim 1. For example, step c of Perez shows substantial distension and stretching of the epithelial layer to form blister 608, and step d of Perez shows a substantial gap extending between the blistered flap (608) and the corneal stromal margin (612).

Therefore, the relevant scope and content of Perez are limited to a flap of tissue that does not substantially fix the lens to the eye.

With regards to the scope and content of Gibson and Kern, Applicants note that these references are cited as teaching “that it was known to secure similar devices within Bowman’s membrane with an adhesive.” Office Action, page 5. Applicants note that claim 81 is amended such that this rejection is now moot in point.

With regards to the scope and content of Simon or Hoffer, the Examiner has relied on Simon or Hoffer as teaching “that it was known to make slits in the eye as small as possible to reduce trauma and healing time”, and that “it would have been obvious to make the incision of Perez as small as possible to reduce trauma and healing time as taught by Simon or Hoffer. Office Action, page 5.

Applicants respectfully submit that Perez teaches a flap and a blister, such that making the incision of Perez smaller would merely result in a small incision in the blistered and distended flap that would be incapable of substantially fixing the lens to the eye with the epithelial cell layer as recited in claim 81. Further neither Simon nor Hoffer teach the lens substantially fixed to the eye with the epithelial cell layer, such that these references fail to overcome the deficiencies of Perez.

In conclusion, significant and unobvious differences exist between the lens substantially fixed to the eye with the epithelial cell layer, as recited in claim 1, and the scope and content of the proposed combination of Perez in view of Gibson or Kern and Simon or Hoffer.

Claims 82-85, 89, 91-92, 94-95, 97-98, 105-106, 108, 182-183, 185, 188, and 191 depend on independent claim 81 and are allowable for at least reasons similar to claim 81

Claims 96, 100-102, 150, 178-179, and 184 stand rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer (as applied above), and further in view of US 4,959,353 in the name of Brown et al. (hereinafter "Brown"). Office Action page 6. Claims 96, 100-102, 150, 178-179, and 184 depend on independent claim 81 and are allowable for at least reasons similar to claim 81.

Claims 121-123, 126, 132, 140, 160, 163-166, 173, and 192 stand rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer (as applied above), and further in view of US 6,335,006 in the name of Miller (hereinafter "Miller"). Office Action page 6. Claims 121-123, 126, 132, 140, 160, 163-166, 173, and 192 depend on independent claim 81 and are allowable for at least reasons similar to claim 81.

Claims 112-113, 124-125, 134-137, and 161-162 stand rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer, and Miller (as applied above), and further in view of US 2003/0220653 in the name of Perez (hereinafter "Perez"). Office Action page 7. Claims 112-113, 124-125, 134-137, and 161-162 depend on independent claim 81 and are allowable for at least reasons similar to claim 81.

Claim 171 stands rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller as applied above, and further in view of US 2004/0015234 (hereinafter "Peyman"). Claim 171 depends on independent claim 81 and is allowable for at least reasons similar to claim 81.

Claim 177 stands rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller as applied above, and further in view of US 4,959,353 (hereinafter "Brown"). Claim 177 depends on independent claim 81 is allowable for at least reasons similar to claim 81.

Claims 180, 192-196, 200-202, 206, and 209 stand rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer (as applied above), and further in view of US 5,984,914 in the name of Cumming (hereinafter "Cumming"). Office

Action page 8. Independent claim 194 has been amended and is allowable for at least reasons similar to claim 81. Claims 180, 192, 193, 195, 196, 200-202, 206 and 209 depend on claims 81 and 194, respectively, and are allowable for at least reasons similar to the dependent claims.

Claim 211 stands rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in view of US 6,361,560 in the name of Nigam (hereinafter "Nigam"). Office Action page 9. Claim 211 depends on independent claim 194 and is allowable for at least reasons similar to claim 194.

Claim 107 stands rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claim 81 above, and further in view of US 2004/0015234 in the name of Peyman (hereinafter "Peyman"). Office Action page 9. Claim 107 depends on independent claim 81 and is allowable for at least reasons similar to claim 81.

Claims 197 and 198 stand rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Hoffer, Simon and Cumming as applied to claim 194 above, and further in view of US 2003/0220653 in the name of Perez (hereinafter "Perez"). Office Action page 9. Claims 197 and 198 depend on independent claim 194 and are allowable for at least reasons similar to claim 194.

Claims 186 and 190 stand rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer as applied to claim 81 above, further in view of US2002/0039788 in the name of Isseroff et al (hereinafter "Isseroff"). Office Action page 10. Claims 186 and 190 depend on claim 81 and are allowable for at least reasons similar to claim 81.

Claims 203 and 208 stand rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in view of Isseroff. Office Action page 10. Claims 203 and 208 depend on independent claim 194 and are allowable for at least reasons similar to claim 194.

Claim 210 stands rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Cumming as applied to claim 194 above, and further in



view of US 4,959,353 in the name of Brown (hereinafter "Brown"). Office Action page 11. Claim 210 depends on independent claim 194 and is allowable for at least reasons similar to claim 194.

Claim 86 stands rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Hoffer, and Simon (as applied above), and further in view of US 4,983,181 in the name of Civerchia (hereinafter "Civerchia"). Office Action page 11. Claim 86 depends on independent claim 81 and is allowable for at least reasons similar to claim 81.

Claims 103 and 104 stand rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, and Hoffer (as applied above), and further in view of US 5,587,175 in the name of Viegas et al. (hereinafter "Viegas"). Office Action page 11. Claims 103 and 104 depend on independent claim 81 and are allowable for at least reasons similar to claim 81.

Claims 212 and 213 stand rejected under 35 USC. 103(a) as allegedly unpatentable over Perez, Simon, Hoffer, and Viegas. Office Action page 12. Independent claim 212 is amended and allowable for at least reasons similar to claim 81. Claim 213 depend on independent claim 212 and is allowable for at least reasons similar to claim 212.

Claims 127-130, 167-170, and 214-221 stand rejected under 35 USC 103(a) as allegedly unpatentable over Perez, Gibson, Kern, Simon, Hoffer and Miller (as applied above), and further in view of Viegas. Office Action page 12. Independent claims 214 and 218 have been amended and are allowable for at least reasons similar to independent claim 81. Claims 127-130, 167-170, and 215-217 and 219-221 depend on independent claims 81, 214 and 218, respectively, and are allowable for at least reasons similar to these independent claims.

#### **New Claims 222-235**

New Claims 222-235 depend on claim 81 and are allowable as reciting additional unobvious combinations of claim elements. The support use and advantages for new claims 222-235 can be found throughout the Application as originally filed. For example with regards to claims 222-227, exemplary embodiments are shown in the Figures, for example Figures 8A-8C


and 11A-11D, and the supporting text, for example pages 40 and 41. Also by example, with regards to new claims 229-231, exemplary embodiments are shown in the Figures, for example Figures 12A-12D, and the supporting text, for example on page 19. With regards to new claims 232-235, exemplary embodiments are shown in the Figures, for example Figures 13A-13C, and the supporting text, for example on pages 16-17 and 24-26.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

  
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